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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/998,491 | 11/30/2001 | Radmila Mileusnic | 3578-120 | 6361 |

23973 7590 10/27/2005

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|----------------------------------|--|
| Office Action Summary | Application No. 09/998,491 | Applicant(s) MILEUSNIC ET AL. | |
| | Examiner Jegatheesan Seharaseyon, Ph.D | Art Unit 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7, 10 and 12-35 is/are pending in the application.
- 4a) Of the above claim(s) 12-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7 is/are allowed.
- 6) ☐ Claim(s) 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/25/2005 has been entered. An action on the RCE follows.
2. Claims 7, 10 and 12-35 are pending. Claims 12-35 remain withdrawn. Claims 7 and 10 have been amended.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112, 1st paragraph

4. Applicants amendments have necessitated the withdrawal of the pending rejection of claims 7 and 10 under 35 U.S.C. 112, 1st paragraph.

Claim Rejections - 35 USC § 102

5. Applicants amendments have necessitated the withdrawal of the pending rejection of claims 7 under 35 U.S.C. 102(b).
6. The rejection of claim 10 as being anticipated by Saitoh et al. (1994) is maintained. Applicants' arguments have been fully considered but are not found to be persuasive. Specifically, Applicants direct the attention of the Office to "(-)" entry for RER in the table at page 18 (Peptide M3). Applicant is suggesting that the reference is teaching away from the invention. Irrespective of the activity indicated by the Applicants, the presence

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of RER peptide in the pharmaceutical composition of Saitoh et al. anticipates the instant invention because the activities of the peptide are inherent to peptide. Note that as long as there is evidence of record establishing inherency, failure of those skilled in the art to contemporaneously recognize an inherent property, function or ingredient of a prior art reference does not preclude a finding of anticipation. *Atlas Powder Co. v. IRECO, Inc.*, 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1948 (Fed. Cir. 1999) (Two prior art references disclosed blasting compositions containing water-in-oil emulsions with identical ingredients to those claimed, in overlapping ranges with the claimed composition. The only element of the claims arguably not present in the prior art compositions was "sufficient aeration . . . entrapped to enhance sensitivity to a substantial degree." The Federal Circuit found that the emulsions described in both references would inevitably and inherently have "sufficient aeration" to sensitize the compound in the claimed ranges based on the evidence of record (including test data and expert testimony). This finding of inherency was not defeated by the fact that one of the references taught away from air entrapment or purposeful aeration.). See also *In re King*, 801 F.2d 1324, 1327, 231 USPQ 136, 139 (Fed. Cir. 1986); *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 782, 227 USPQ 773, 778 (Fed. Cir. 1985). Therefore the rejections of record are maintained.

7. Claim 7 is allowable. Claim 10 remains rejected.

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Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSS 10/05


JANET L. ANDRES
SUPERVISORY PATENT EXAMINER